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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/527,140   | 10/19/2005  | Toshiyuki Hayase     | SHIG CPTA1402AU     | 9503             |
| 27667  | 7590        | 02/13/2008           | EXAMINER            |                  |
| HAYES SOLOWAY P.C.<br>3450 E. SUNRISE DRIVE, SUITE 140<br>TUCSON, AZ 85718 |             |                      | CWERN, JONATHAN     |                  |
|  |             | ART UNIT             | PAPER NUMBER        |                  |
|  |             | 3737                 |                     |                  |
|  |             | MAIL DATE            | DELIVERY MODE       |                  |
|  |             | 02/13/2008           | PAPER               |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/527,140             | HAYASE ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Jonathan G. Cwern      | 3737                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 1/15/08.
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,3-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1, 3-4 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Claim Objections***

Claims 1, and 3-4 are objected to because of the following informalities: In claim 1, line 4, "the reflected ultrasonic signal" lacks antecedent basis. In claim 1, line 13, "the blood flow domain" lacks antecedent basis. In claim 3, line 2, "the actual feedback" lacks antecedent basis. In claims 3 and 4, all parameters used in the equations should be defined. Also, claims 3 and 4 merely include mathematical equations, no additional structure has been set forth. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Charbel et al. (US 7191110) in view of Okada et al. (US 6673020).

Charbel et al. show, a blood flow visualizing diagnostic apparatus characterized by having: an analysis processing unit which obtains a blood vessel shape (measuring blood vessels, column 13, line 10-50; also column 17, lines 65-67) and a blood flow velocity (measuring blood velocity, column 15, line 45-column 16, line 30; also column 18, lines 1-2 where blood flow constitutes blood velocity) in the blood vessel by the received signal; a simulation unit which sets computational lattices on the basis of the blood vessel shape obtained by said analysis processing unit to simulate the blood flow velocity and a pressure distribution (the polygonal mesh iso-surface can be considered a lattice or the cube could also be considered a lattice, it is generated based on the shape of the blood vessel, and is used to simulate the velocity and pressure, column 14, lines 5-column 18, line 6); a feedback unit which computes an error between the blood flow velocity obtained by said analysis processing unit and the blood flow velocity obtained by said simulation unit to feed back the error to said simulation unit (the actual data is used to update the simulated model based on the specific patient data, the actual data is fed back to the model and used to adjust the model, although the word "error" is not specifically used, the adjusting of the model based on patient data can be taken to mean that any error between the simulated model and the actual patient data is corrected, column 17, 55-column 18, line 5); and a display unit which displays the blood flow velocity and the pressure distribution output from said simulation unit after the feedback (column 16, lines 30-45). Also, the feedback unit performs the feedback to a

sufficiently large number of representative points which are distributed over the blood flow domain in said computational lattices (A “sufficient” number of points are a number of points that are adequate to complete the task, which in this case is generating a customized patient model. Because the obtained result is in fact a model customized to the patient, a “sufficient” number of points must have been adjusted to achieve a customized patient model, column 17, line 55-column 18, line 5); and using ultrasound to measure the blood velocity (column 16, lines 20-25)

Okada et al. disclose an ultrasonic diagnostic apparatus. Okada et al. teach, an ultrasonic measurement unit which emits an ultrasonic signal toward a blood vessel inside a human body to receive the reflected ultrasonic signal (using ultrasound to obtain the size of blood vessels, the velocity of the blood, and the blood pressure, column 2, line 60-column 4, line 60).

It would have been obvious to one of ordinary skill in the art, at the time the invention as made, to have used ultrasound to measure the shape of the blood vessels, the blood velocity, and the blood pressure as taught by Okada et al., in the system of Charbel et al., with the motivation that ultrasound provides for a suitable and non-invasive imaging means to image blood vessels. Charbel et al. does in fact use Doppler in his blood flow measurements as well, and while no specific mention is made of using ultrasound to obtain the vessel shape, one of ordinary skill in the art would know that ultrasound imaging provides a suitable means to image blood vessels. There is a reasonable expectation of success to combine these references, because both are

related to measuring blood vessel shape, blood velocity, and blood pressure in a patient.

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charbel et al. (US 7191110) in view of Okada et al. (US 6673020) as applied to claim 1 above, and further in view of Hayase et al. ("Numerical Realization of Flow Field by Integrating Computation and Measurement, Proceedings of 5<sup>th</sup> World Congress on Computational Mechanics, Vienna, Austria, July 7-12 (2002).

Hayase et al. disclose a numerical realization of flow field. Hayase et al. teach a similar equation to claim 4 where the Navier-Stokes equation includes a component f, the body force corresponding to the feedback signal (page 4). There is a similar equation to claim 3 where the body force is calculated by multiplying a negative value of the feedback gain with the pressure components (page 5). One of ordinary skill in the art calculating velocity of blood could have substituted appropriate values for blood flow as opposed to the pressure.

It would have been obvious to one of ordinary skill in the art, to have computed the feedback component as taught by Hayase et al., in the combined system of Charbel et al. and Okada et al. Charbel et al. show that actual values of blood flow can be used to update a simulation model. In the absence of any criticality or unexpected result, it would be an obvious design choice to have performed the calculations another way.

***Response to Arguments***

Applicant's arguments filed 1/15/08 have been fully considered but they are not persuasive.

In regards to applicant's argument that Charbel et al. do not show feedback of the blood flow velocity, examiner respectfully disagrees. In the last line of the cited passage, quoted by applicant, Charbel et al. show "a knowledge of the actual arterial structure and actual blood flows can be used to customize the model to the actual patient". This meets the claimed limitation. It is not necessary for Charbel et al. to explicitly use the word "feedback". Charbel et al. show a simulation model, and then using actual values of blood flow from a patient to customize the model to that patient. Adjusting the model with actual values of bloodflow is "feedback". Bloodflow is described earlier as being determined by measuring blood velocity (column 16, lines 10-16).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is (571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. G. C./  
Examiner, Art Unit 3737

/Ruth S. Smith/  
Primary Examiner, Art Unit 3737